

§ 872.3940

such as biological response modifiers, require premarket approval.

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required.* Devices described in paragraph (b)(2) of this section shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[70 FR 21949, Apr. 28, 2005]

§ 872.3940 Total temporomandibular joint prosthesis.

(a) *Identification.* A total temporomandibular joint prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and augment the glenoid fossa to functionally reconstruct the temporomandibular joint.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any total temporomandibular joint prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a total temporomandibular joint prosthesis that was in commercial distribution before May 28, 1976. Any other total temporomandibular joint prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[59 FR 65478, Dec. 20, 1994, as amended at 63 FR 71746, Dec. 30, 1998]

§ 872.3950 Glenoid fossa prosthesis.

(a) *Identification.* A glenoid fossa prosthesis is a device that is intended to be implanted in the temporomandibular joint to augment a glenoid fossa or to provide an articulation surface for the head of a mandibular condyle.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any glenoid fossa prosthesis that was

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in commercial distribution before May 28, 1976, or that has on or before March 30, 1999, been found to be substantially equivalent to a glenoid fossa prosthesis that was in commercial distribution before May 28, 1976. Any other glenoid fossa prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[59 FR 65478, Dec. 20, 1994, as amended at 63 FR 71746, Dec. 30, 1998]

§ 872.3960 Mandibular condyle prosthesis.

(a) *Identification.* A mandibular condyle prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a glenoid fossa.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any mandibular condyle prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a mandibular condyle prosthesis that was in commercial distribution before May 28, 1976. Any other mandibular condyle prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[59 FR 65478, Dec. 20, 1994, as amended at 63 FR 71746, Dec. 30, 1998; 78 FR 79310, Dec. 30, 2013]

§ 872.3970 Interarticular disc prosthesis (interpositional implant).

(a) *Identification.* An interarticular disc prosthesis (interpositional implant) is a device that is intended to be an interface between the natural articulating surface of the mandibular condyle and glenoid fossa.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any interarticular disc prosthesis (interpositional implant) that was in